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Exhibit 21A

U.S. Department of Justice

United States Attorney
Western District of Virginia

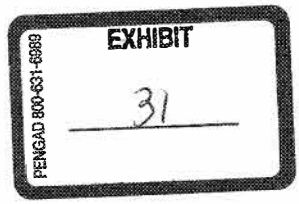
STATEMENT OF UNITED STATES ATTORNEY JOHN BROWNLEE ON THE GUILTY PLEA OF THE PURDUE FREDERICK COMPANY AND ITS EXECUTIVES FOR ILLEGALLY MISBRANDING OXYCONTIN

May 10, 2007

One of the oldest and most challenging medical mysteries is the treatment of pain. For centuries, scientists and doctors have searched for a drug that would safely relieve patients of their chronic pain without inflicting the dangerous side effects that routinely come from the use of addictive narcotics. The discovery of this "wonder" drug would bring hope and relief to millions of suffering patients and wealth beyond one's imagination to its creators.

In 1996, Purdue and its top executives claimed that they had developed such a drug; a safe drug that would help those suffering in pain. The name of that drug was OxyContin. Backed by an aggressive marketing campaign, Purdue's OxyContin became the new pain medication of choice for many doctors and patients. Purdue claimed it had created the miracle drug – a low risk drug that could provide long acting pain relief but was less addictive and less subject to abuse. Purdue's marketing campaign worked, and sales for OxyContin skyrocketed – making billions for Purdue and millions for its top executives.

But OxyContin offered no miracles to those suffering in pain. Purdue's claims that OxyContin was less addictive and less subject to abuse and diversion were false – and Purdue knew



its claims were false. The result of their misrepresentations and crimes sparked one of our nation's greatest prescription drug failures. OxyContin is nothing more than pure oxycodone – a habit forming narcotic derived from the opium poppy. Purdue's OxyContin never lived up to its hype and never offered a low risk way of reducing pain as promised. Simply put, the genesis of OxyContin was not the result of good science or laboratory experiment. OxyContin was the child of marketeers and bottom line financial decision making.

Accordingly, this morning, in a federal courtroom in Abingdon, Virginia, the Purdue Frederick Company, the manufacturer and distributor of OxyContin, pleaded guilty to a felony charge of illegally misbranding OxyContin in an effort to mislead and defraud physicians and consumers. Purdue has agreed to pay over $600 million in criminal and civil penalties, fines and forfeitures, subjected itself to independent monitoring and an extensive remedial action program, and acknowledged that it illegally marketed and promoted OxyContin by falsely claiming that OxyContin was less addictive, less subject to abuse and diversion, and less likely to cause withdrawal symptoms than other pain medications – all in an effort to maximize its profits. Also, Purdue's Chief Executive Officer Michael Friedman, General Counsel Howard Udell, and former Chief Medical Officer Paul Goldenheim pleaded guilty to a misdemeanor charge of misbranding OxyContin and collectively agreed to pay $34.5 million in penalties. With its OxyContin, Purdue unleashed a highly abusable, addictive, and potentially dangerous drug on an unsuspecting and unknowing public. For these misrepresentations and crimes, Purdue and its executives have been brought to justice.

We have released a Criminal Information, Plea Agreements, a Corporate Integrity Agreement, a Statement of Facts, and a Complaint for Forfeiture that have been filed in U.S. District Court in Abingdon. Purdue and its top three executives have pleaded guilty to illegally misbranding

OxyContin from 1996 thru 2001. The company has admitted that it misbranded OxyContin with the intent to defraud and mislead the public.

As part of this plea agreement, Purdue and its top three executives will pay $634.5 million in criminal and civil fines, penalties, and forfeitures, to be distributed as follows. First, Purdue will forfeit to the United States $276.1 million, a portion of which will be shared with the state and federal law enforcement agencies for their work during this investigation.

Second, Purdue will pay $130 million for compensation and settlement of private civil liabilities related to OxyContin. Any part of the $130 million that Purdue fails to distribute within two years will be immediately paid to the United States. Third, Purdue will pay $100.6 million to the United States as reimbursement for payments made by government agencies for the settlement of false claims related to the misbranding of OxyContin. Those federal agencies include the Department of Health and Human Services, the Department of Labor, the Department of Defense, the Office Personnel Management, and the Veterans Administration.

Fourth, Purdue will pay $59.3 million to the State Medicaid programs as reimbursement for payments made by Medicaid for the settlement of false claims related to the misbranding of OxyContin. This money is available to any state to settle claims related to Purdue's criminal conduct. Fifth, Purdue and its top three executives will pay $39.8 million to the Virginia Attorney General's Medicaid Fraud Control Unit Program Income fund. Virginia's MFCU is an important partner in our efforts to fight fraud against our medicaid programs. Sixth, Purdue will pay $20 million to the Virginia Department of Health Professionals' operation of the Virginia Prescription Monitoring Program. The prescription monitoring program was initiated in part because of the big spike in prescription drug abuse that accompanied the illegal marketing of OxyContin. Currently,

the program is largely funded by the Virginia taxpayers, and the $20 million payment by Purdue should endow the program for the foreseeable future. Seventh, Purdue will pay $4.6 million to cover the costs of the five year internal monitoring program that is a part of the company's Corporate Integrity Agreement with the Health and Human Services Office of the Inspector General. Eighth, Purdue will pay $3.4 million to the federal and state Medicaid programs for improperly calculated Medicaid rebates for years 1998 and 1999, and finally, Purdue and the three executives will pay $515,475 in criminal fines and special assessments to the court.

In addition to the guilty pleas and monetary penalties, the United States has directed Purdue, as part of the Corporate Integrity Agreement, to retain and pay for an Independent Monitor and staff to monitor Purdue's compliance with this agreement and federal law. The monitor and staff will be independent from Purdue's management and must file periodic reports with the government concerning Purdue's conduct and business practices. We believe this monitoring program, in conjunction with the Corporate Integrity Agreement, will ensure that in the future Purdue will market and promote its products in an honest and responsible manner. The public must be confident that we will keep close watch on how Purdue sells its most dangerous products.

I would now like to provide to you a brief summary of the investigation and some of our findings. The main violations of the law revealed by the government's criminal investigation are set forth in detail in the Statement of Facts released to you today.

The defendant The Purdue Frederick Company, a New York corporation headquartered in Connecticut, was created in 1892 and purchased by its current owners in 1952. Defendant Michael Friedman joined Purdue in 1985 and was appointed President and Chief Executive Officer in 2003. It is our understanding that Mr. Friedman has announced his intention to leave Purdue this year.

Defendant Howard Udell joined Purdue in 1977 and is presently Purdue's Executive Vice President and Chief Legal Officer. Defendant Dr. Paul Goldenheim joined Purdue in 1985 as its Medical Director. Dr. Goldenheim left Purdue in 2004.

This case began in early 1995, when Purdue used focus groups of primary care physicians and surgeons to determine whether physicians would be willing to prescribe OxyContin for patients with non-cancer pain. According to Purdue's research, many of these physicians had great reservations about prescribing OxyContin because of the drug's addictive potential and side effect profile, and its abuse potential. It was clear from these focus groups that physicians were concerned about the safety and risks of OxyContin.

Purdue also learned from these focus groups that physicians wanted a long lasting pain reliever that was less addictive and less subject to abuse and diversion. Purdue understood that the company that marketed and sold that drug would dominate the pain management market. And that is exactly what Purdue tried to do.

Despite knowing that OxyContin contained high concentrations of oxycodone HCL, had an abuse potential similar to that of morphine, and was at least as addictive as other pain medications on the market, Purdue, beginning in January 1996, with the intent to defraud and mislead, falsely marketed and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications. Purdue did so in the following ways:

First, Purdue trained its sales representatives to falsely inform health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse. Purdue ordered this training even though its own study showed that a drug abuser

could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by simply crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

Second, Purdue falsely instructed its sales representatives to inform health care providers that OxyContin could create fewer chances for addiction than immediate-release opioids.

Third, Purdue sponsored training that falsely taught Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids.

Fourth, Purdue falsely told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug.

And fifth, Purdue falsely told health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

The results of Purdue's crimes were staggering. According to DEA, the number of oxycodone related deaths increased 400 percent between 1996 and 2001. During that same time period, the annual number of prescriptions for OxyContin increased from approximately 300,000 to nearly 6 million. Also, in February of 2002, the DEA released a report detailing the death rates caused by OxyContin abuse up to that time. According to the DEA, there were 146 deaths in which OxyContin was determined to be the direct "cause of" or "a contributing factor to." DEA identified an additional 318 deaths that were "most likely" caused by OxyContin. In Virginia, our medical examiner reported that 228 people died in western Virginia from overdoses of oxycodone from 1996

to 2005.

For some communities, the danger went beyond just addiction and death. Beginning in 2000, localities began to report dramatically higher crime rates – some up as much as 75% from the year before. This sharp increase in crime was directly attributable to the abuse of OxyContin. Tazewell County estimated that OxyContin was behind 80-95% of all crimes that were committed there. From 1998 to 2003, burglaries, robberies, and larcenies jumped 131% in Buchanan County and 102% in Russell County.

During the last 10 years, Virginia's law enforcement community has fought hard against the devastating effects OxyContin has had on our citizens and communities. During that time, we have convicted the OxyContin addicts who committed serious crimes to get money to buy more OxyContin, and we convicted street dealers who preyed upon the addicts' craving for this powerful narcotic. We also convicted pharmacists and physicians who illegally diverted OxyContin for personal gain and profit. With today's conviction of the maker of OxyContin, we have finally brought to justice the main component involved in this ring of abuse. The conviction of Purdue and its executives will end the misbranding and fraudulent marketing of OxyContin, deter other companies from committing like crimes, and provide desperately needed resources to fight addiction and abuse that threatens the health of millions of Virginians.

Thank you.

NEWS RELEASE

UNITED STATES ATTORNEY'S OFFICE
WESTERN DISTRICT OF VIRGINIA

John L. Brownlee
United States Attorney

Heidi Coy
Public Affairs Specialist

BB&T Building
310 First Street, S.W., Room 906
Roanoke, Virginia 24011-1935
Phone: (540) 857-2974
FAX: (540) 857-2179

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THE PURDUE FREDERICK COMPANY, INC. AND TOP EXECUTIVES PLEAD GUILTY TO MISBRANDING OXYCONTIN; WILL PAY OVER $600 MILLION

John L. Brownlee, United States Attorney for the Western District of Virginia, and Virginia Attorney General Bob McDonnell announced today that The Purdue Frederick Company, Inc., along with its President, Chief Legal Officer, and former Chief Medical Officer have pleaded guilty to charges of misbranding Purdue's addictive and highly abusable drug OxyContin. Purdue and the three executives will pay a total of $634,515,475. OxyContin is a Schedule II prescription pain relief medication, classified as having the highest potential for abuse of legally available drugs. The Purdue Frederick Company, Inc., and the three executives have admitted that Purdue fraudulently marketed OxyContin by falsely claiming that OxyContin was less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than other pain medications when there was no medical research to support these claims and without Food and Drug Administration approval of these claims.

"Even in the face of warnings from health care professionals, the media, and members of its own sales force that OxyContin was being widely abused and causing harm to our citizens, Purdue, under the leadership of its top executives, continued to push a fraudulent marketing campaign that promoted Oxycontin as less addictive, less subject to abuse, and less likely to cause withdrawal, " said United States Attorney John Brownlee. "In the process, scores died as a result of OxyContin abuse and an even greater number of people became addicted to OxyContin; a drug that Purdue led many to believe was safer, less abusable, and less addictive than other pain medications on the market. Today's convictions are a testament to the outstanding work of the prosecutors and agents who spent years investigating this important case."

The Purdue Frederick Company, Inc. and Purdue Pharma, L.P. are part of a worldwide group of related and associated entities engaged in the pharmaceutical business. These entities manufacture, market, and distribute OxyContin, an extended-release form of oxycodone.

"Purdue put its desire to sell OxyContin above the interests of the public," said Assistant Attorney General Peter D. Keisler. "Purdue abused the drug approval process which relies on drug manufacturers to be forthright in reporting clinical data and, instead, misled physicians about the addiction and withdrawal issues involved with Oxycontin."

"The criminal behavior exhibited in this case damages the reputation of a critically important industry. Pharmaceutical companies have an obligation to patients, physicians, and those in the industry they serve to market prescription drugs in accordance with the law and FDA regulations." said Virginia Attorney General Bob McDonnell, "I applaud John Brownlee and his team for their leadership, as well as the Virginia Medicaid Fraud Control Unit, FDA and all of the other state and federal law enforcement agencies that worked so hard over the past four years to investigate this complex criminal scheme and bring the wrongdoers to justice."

"FDA will not tolerate practices that falsely promote drug products and place consumers at health risk," said Margaret O.K. Glavin, Associate Commissioner for Regulatory Affairs, FDA. "We will continue to do all we can to protect the public against drug companies and their representatives who are not truthful and bilk consumers of precious health care dollars."

The Purdue Frederick Company, Inc., pleaded guilty to felony misbranding OxyContin with the intent to defraud and mislead. President and Chief Operating Officer Michael Friedman, Executive Vice President and Chief Legal Officer Howard Udell, and former Executive Vice President of Worldwide Medical Affairs Paul D. Goldenheim, pleaded guilty to a misdemeanor charge of misbranding OxyContin. All the pleas were entered in United States District Court in Abingdon this morning.

"Purdue's illegal sales and marketing practices concealed information from patients and many health care providers regarding the potency and abuse potential of OxyContin for corporate profit," said Daniel R. Levinson, Inspector General for the U.S. Department of Health and Human Services. "We commend the highly qualified team of prosecutors and investigators from a variety of Federal and State agencies for developing a global resolution that addresses the criminal violations of the past, ensures strict compliance in the future, and serves as a strong warning to others who may consider illegally marketing pharmaceuticals."

"The falsification of drug product information is a very serious breach of the public's trust. IRS Criminal Investigation will continue to concentrate its resources on the tax and money laundering aspects of these types of investigations in cooperation with the United States Attorney's Office and other federal, state, and local authorities," said Charles R. Pine, Special Agent in Charge.

"Today's guilty pleas mark a significant milestone in the fight against corruption by company officials who seek to illegally enrich corporate profits at taxpayers' expense," stated Gordon S. Heddell, Inspector General, U.S. Department of Labor. "These convictions demonstrate our steadfast resolve to investigate any individuals who would defraud Labor programs, such as the Office of Workers' Compensation Programs, by overcharging them. My office remains committed to working with other law enforcement agencies and the U.S. Attorney to fight this type of corruption."

Pursuant to written plea agreements, Purdue and the executives will pay a total of $634,515,475.00. Purdue's payments will include:

$276.1 million forfeited to the United States

$160 million paid to federal and state government agencies to resolve liability for false claims made to Medicaid and other government healthcare programs

$130 million set aside to resolve private civil claims (monies remaining after 36 months will be paid to the United States)

$5.3 million paid to the Virginia Attorney General's Medicaid Fraud Control Unit to fund future health care fraud investigations

$20 million paid to fund the Virginia Prescription Monitoring Program for the foreseeable future

In addition, Purdue will pay the maximum statutory criminal fine of $500,000.

Purdue's top executives will pay the following amounts to the Virginia Attorney General's Medicaid Fraud Control Unit:

$19 million paid by Michael Friedman

$8 million paid by Howard R. Udell

$7.5 million paid by Dr. Paul D. Goldenheim

Each executive will also pay a $5,000 criminal fine.

The Director of the Defense Criminal Investigative Service, Mr. Chuck Beardall, stated, "It is unthinkable that purely for greed, addictive drugs were fraudulently marketed to the public, and in so doing threatened the health and safety of our citizens. Among those endangered were soldiers, sailors, airmen, marines, and their families, all of whom avail themselves of the military health system. At a time when our military personnel and their loved ones are sacrificing so much, something like this is incomprehensible and grossly reprehensible."

According to the Statement of Facts filed with the Court, beginning in January 1996 and continuing through June 30, 2001, Purdue's market research found that "[t]he biggest negative of [OxyContin] was the abuse potential." Despite this finding, Purdue's supervisors and employees falsely and misleadingly marketed OxyContin as less addictive, less subject to abuse, and less likely to cause withdrawal than other pain medications. Purdue misbranded OxyContin in three specific ways:

1. Purdue sales representatives falsely told some health care providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids. This message was

presented to some health care providers through the use of graphs that exaggerated the differences between blood plasma levels achieved by OxyContin compared to the levels of other pain relief medications. Purdue supervisors and employees participated in the misbranding in the following ways:

A. Purdue supervisors and employees sponsored training that used graphs that exaggerated the differences between the blood plasma levels of OxyContin as compared to immediate-release opioids. These graphs were used to falsely teach Purdue sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids and that would result in less euphoria and less potential for abuse than short-acting opioids.

B. Purdue supervisors and employees permitted new Purdue sales representatives to use similar exaggerated graphical depictions during role-play training at Purdue's headquarters in Stamford, Connecticut.

2. Purdue supervisors and employees drafted an article about a study of the use of OxyContin in osteoarthritis patients that was published in a medical journal on March 27, 2000. On June 26, 2000, each sales representative was provided a copy of the article together with a "marketing tip" that stated that the article was available for use in achieving sales success. Sales representatives distributed copies of the article to health care providers to falsely or misleadingly represent that patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms. The article also indicated that patients on such doses would not develop tolerance. The marketing tip that accompanied the article stated that one of the twelve key points was, "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR [controlled release] oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR oxycodone at doses below 60 mg/d [milligrams per day] can be discontinued without tapering the dose if the patient condition so warrants." These marketing claims were made even though Purdue representatives were well aware of the following information:

A. The year before the article was published and distributed to sales representatives, Purdue received an analysis of the osteoarthritis study and a second study from a United Kingdom company affiliated with Purdue that listed eight patients in the osteoarthritis study "who had symptoms recorded that may possibly have been related to opioid withdrawal," and stated that "[a]s expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided."

B. In May of 2000, Purdue received a report of a patient who said he or she was unable to stop taking OxyContin 10 mg every 12 hours without experiencing withdrawal symptoms. Executives also learned that "this type of question,

patients not being able to stop OxyContin without withdrawal symptoms ha[d] come up quite a bit . . . in Medical Services lately (at least 3 calls in the last 2 days)."

C. In February 2001, Purdue received a review of the accuracy of the withdrawal data in the osteoarthritis study that listed eleven study patients who reported adverse experience due to possible withdrawal symptoms during the study's respite periods and stated "[u]pon a review of all comments for all enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms;" Even after receiving this information, on March 28, 2001, supervisors and employees decided not to write up the findings because of a concern that it might "add to the current negative press."

D. Supervisors and employees stated that while they were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything "to make physicians think that oxycodone was stronger to or equal to morphine" or to "take any steps in the form of promotional materials, symposia, clinicals, publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians[']mind[s]."

3. Purdue sales representatives, while promoting and marketing OxyContin, falsely told health care providers that the statement in the OxyContin package insert that "[d]elayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug," meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

The statement was later amended to read, "[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is believed to reduce the abuse liability of a drug." Nevertheless, Purdue continued to market OxyContin in the same manner as described above.

Purdue supervisors and employees took part in the misbranding in the following ways:

A. Supervisors instructed Purdue sales representatives to use the reduced abuse liability statement and the amended statement to market and promote OxyContin.

B. Supervisors told Purdue sales representatives they could tell health care providers that OxyContin potentially creates less chances for addiction than immediate-release opioids.

C. Supervisors trained Purdue sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although Purdue's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet merely by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe.

D. By March 2000, Purdue had received reports of OxyContin abuse and diversion occurring in different communities but allowed sales staff to continue promoting and marketing OxyContin in this manner.

The case was investigated by the Virginia Attorney General's Medicaid Fraud Control Unit; Food and Drug Administration, Office of Criminal Investigations; Internal Revenue Service Criminal Investigation; the Department of Health and Human Services Office of Inspector General; Department of Labor, Office of Inspector General; Defense Criminal Investigative Service; Virginia State Police; and West Virginia State Police. The case was prosecuted by Assistant United States Attorneys Rick Mountcastle, Randy Ramseyer and Sharon Burnham and U.S. Department of Justice, Office of Consumer Litigation, Trial Attorneys Barbara Wells and Elizabeth Stein.

END

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	Dkt. No. _____
	)	
THE PURDUE FREDERICK COMPANY, INC.	)	21 U.S.C. §§ 331(a), 352(a), 333(a)(2)
D/B/A The Purdue Frederick Company	)	
MICHAEL FRIEDMAN	)	21 U.S.C. §§ 331(a), 352(a), 333(a)(1)
HOWARD R. UDELL	)	21 U.S.C. §§ 331(a), 352(a), 333(a)(1)
PAUL D. GOLDENHEIM	)	21 U.S.C. §§ 331(a), 352(a), 333(a)(1)

INFORMATION

INTRODUCTION

The United States Attorney charges that at all times relevant to this Information:

Description of Defendants

1. Defendant The PURDUE FREDERICK COMPANY, INC. (referred to in this Information as "PURDUE"), doing business as The Purdue Frederick Company, was a New York corporation, headquartered in Connecticut. It was created in 1892 and was purchased by its current owners in 1952. At all times relevant to this Information, PURDUE and other related and associated entities were engaged in the pharmaceutical business throughout the United States.

2. PURDUE developed and originally marketed OxyContin Tablets ("OxyContin"), an opioid analgesic approved to be taken every twelve hours. OxyContin is a controlled-release form of oxycodone and is a Schedule II controlled substance with an abuse liability similar to morphine.

3. Defendant MICHAEL FRIEDMAN joined PURDUE in 1985 as Vice President and Assistant to the President and Chairman. He was appointed Group Vice President in 1988, Executive Vice President and Chief Operating Officer in 1999, and President and Chief Executive

Officer in 2003.

4. Defendant HOWARD R. UDELL joined PURDUE in 1977 as General Counsel. He was appointed Group Vice President and General Counsel in 1989, Executive Vice President and General Counsel in 1999, and Executive Vice President and Chief Legal Officer in 2003.

5. Defendant PAUL D. GOLDENHEIM joined PURDUE in 1985 as Medical Director. He was appointed Vice President and Medical Director in 1986, Vice President of Scientific and Medical Affairs and Executive Director of Purdue Frederick Research Center in 1988, Group Vice President of Scientific and Medical Affairs in 1989, Executive Vice President of Medical and Scientific Affairs in 1999, Executive Vice President of Worldwide Research & Development in 2000, and Executive Vice President of Worldwide Research & Development and Chief Scientific Officer in 2003. He left PURDUE in 2004.

6. From January 1996 through June 30, 2001, PURDUE received approximately $2.8 billion in revenue from the sale of OxyContin.

Statutory Framework

7. The United States Food and Drug Administration ("FDA") is the agency of the United States responsible for protecting the public health by ensuring the safety, efficacy, and security of human drugs and for enforcing the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*

8. The FDCA, 21 U.S.C. § 355, required a sponsor of a new drug to receive FDA approval of a New Drug Application ("NDA"), before the sponsor could distribute the drug in interstate commerce.

9. The FDCA, 21 U.S.C. § 321(m), defined labeling to include "all labels and other

written, printed, or graphic matter . . . accompanying [a drug]." Title 21, Code of Federal Regulations, Section 202.1(*l*)(2) provided that labeling included brochures, booklets, mailing pieces, detailing pieces, bulletins, letters, motion picture films, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug which were disseminated by or on behalf of a drug's manufacturer, packer, or distributor. Such items "accompanied" a drug if they were designed for use and used in the distribution and sale of the drug.

10. The FDCA, 21 U.S.C. § 352(a), provided that a drug was misbranded "[i]f its labeling [was] false or misleading in any particular." The FDCA, 21 U.S.C. § 321(n), provided that "[i]n determining whether the labeling . . . [was] misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representation or material with respect to the consequences which may result from the use . . . to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual."

11. The FDCA, 21 U.S.C. § 331(a), prohibited the introduction or delivery for introduction into interstate commerce of a misbranded drug. 21 U.S.C. § 333(a)(2) provided that such a violation committed with the intent to defraud or mislead was punishable as a felony. Under 21 U.S.C. § 333(a)(1) and the applicable case law, an individual could be held criminally liable for a misdemeanor violation of § 331(a) without having knowledge of, or intent to cause, the misbranding if that individual was a responsible corporate officer at the time of the misbranding. A responsible corporate officer for these purposes was one who had responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the

misbranding of a drug introduced or delivered for introduction into interstate commerce.

12. OxyContin was a drug within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), and a new drug within the meaning of 21 U.S.C. § 321(p).

OxyContin Approval and Package Insert

13. On approximately December 28, 1994, PURDUE submitted the OxyContin NDA to the FDA. The NDA included clinical studies showing that OxyContin, when dosed every twelve hours, was as safe and as effective as immediate-release oxycodone dosed every six hours.

14. The NDA did not claim that OxyContin was safer or more effective than immediate-release oxycodone or other pain medications and PURDUE did not have, and did not provide the FDA with, any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications.

15. On or about October 24, 1995, the FDA completed, with PURDUE's assistance, an internal Medical Officer Review ("MOR") of the Integrated Summary of Safety ("ISS") and a MOR of the Integrated Summary of Efficacy ("ISE"). While not binding on the company, the MORs were disclosed to certain PURDUE supervisors and employees. These MORs did not state that OxyContin was more effective than or superior to, safer, had less opioid effects, or caused fewer adverse events than any other marketed product.

16. The MOR of the ISS included these statements:

a. "The blood level data in clinical use suggests the opioid effects [of OxyContin and immediate-release oxycodone] would be similar;"

b. "The best conclusion is that the efficacy of [OxyContin] is equivalent to the [immediate-release oxycodone], with an adverse event profile that is as good as the [immediate-release oxycodone]. I would not allow a 'better' claim." (emphasis in original);

c. "The adverse experience profile of [OxyContin] is qualitatively similar to that of the parent drug, oxycodone;" and

d. "Withdrawal is possible in patients who have their dosage abruptly reduced or discontinued."

17. The MOR of the ISE included these statements:

a. "There is some evidence, both pharmacokinetic and clinical, that reduced acute opioid adverse effects may be expected in some patients, but there is not enough evidence to support an [adverse event] superiority claim [for OxyContin] against other marketed products." (emphasis in original); and

b. "Care should be taken to limit competitive promotion. [OxyContin] has been shown to be as good as current therapy, but has not been shown to have a significant advantage beyond reduction in frequency of dosing."

18. The FDA approved the OxyContin NDA on December 12, 1995, and from 1996 through June 30, 2001, the FDA-approved package insert for OxyContin stated that it was intended for "the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." The package insert also included the statement: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."

Misbranding of OxyContin

19. During the period February through March 1995, PURDUE supervisors and employees obtained market research that included focus groups of forty primary care physicians, rheumatologists, and surgeons to determine their receptivity to using OxyContin for non-cancer pain. According to this market research, some of these physicians had concerns, similar to their concerns about combination opioids, regarding OxyContin's addictive potential and side effect profile, including that "[t]he biggest negative of [OxyContin] was the abuse potential."

20. Beginning on or about December 12, 1995, and continuing until on or about June 30, 2001, certain PURDUE supervisors and employees, with the intent to defraud or mislead, marketed

and promoted OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications, as follows:

a. Trained PURDUE sales representatives and told some health care providers that it was more difficult to extract the oxycodone from an OxyContin tablet for the purpose of intravenous abuse, although PURDUE's own study showed that a drug abuser could extract approximately 68% of the oxycodone from a single 10 mg OxyContin tablet by crushing the tablet, stirring it in water, and drawing the solution through cotton into a syringe;

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c. Sponsored training that taught PURDUE sales supervisors that OxyContin had fewer "peak and trough" blood level effects than immediate-release opioids resulting in less euphoria and less potential for abuse than short-acting opioids;

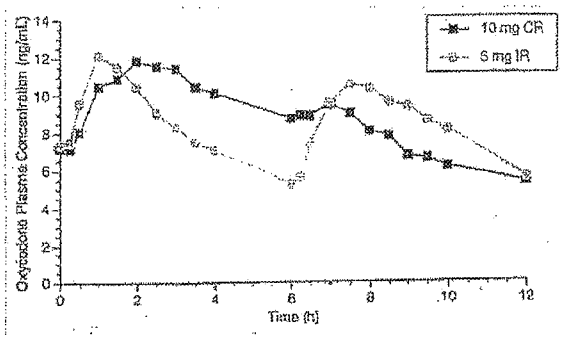
d. Told certain health care providers that patients could stop therapy abruptly without experiencing withdrawal symptoms and that patients who took OxyContin would not develop tolerance to the drug; and

e. Told certain health care providers that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

Misbranding of OxyContin: Use of Graphical Depictions by Sales Representatives

21. Data from one of PURDUE's clinical studies was used to create the following graphical demonstration of the difference in the plasma levels at steady state between patients who

took OxyContin every twelve hours (the "10 mg CR" line) and patients who took immediate-release oxycodone every six hours (the "5 mg IR" line):



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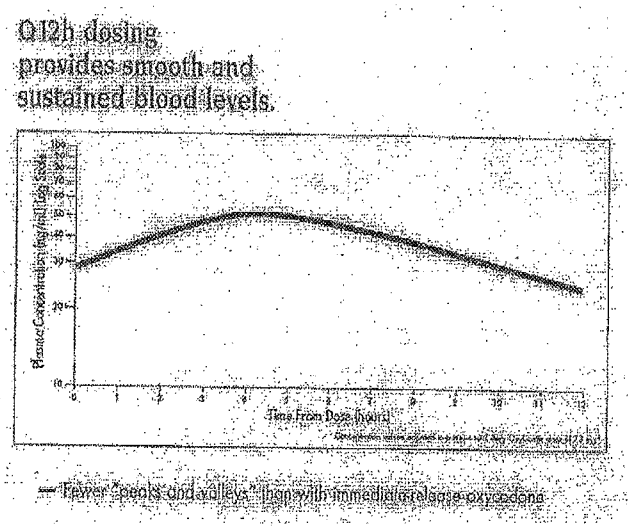

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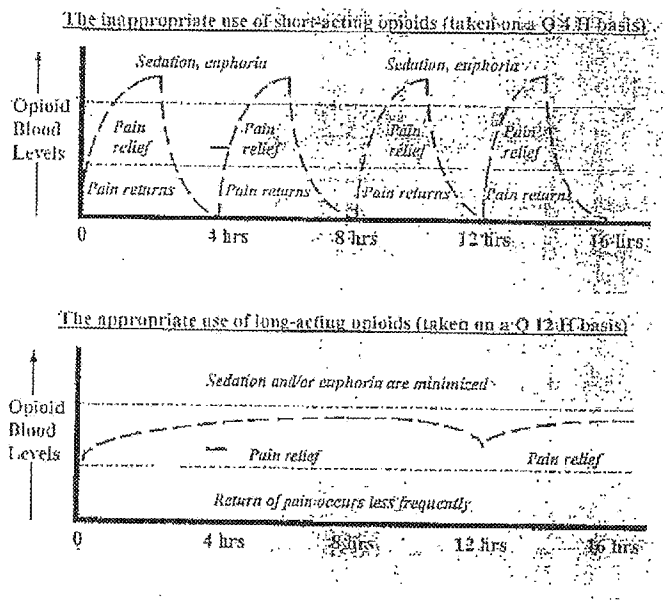

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27. During the period 1999 through June 30, 2001, certain PURDUE sales representatives used graphical depictions similar to the one described in paragraph 25 of the Introduction of this Information and falsely stated to some health care providers that OxyContin had less euphoric effect and less abuse potential than short-acting opioids.

Misbranding of OxyContin: Misleading Use of Article to Claim No Withdrawal or Tolerance

28. On or about January 16, 1997, certain PURDUE supervisors and employees sent to the FDA the results of a clinical study pertaining to the use of low doses of OxyContin by

osteoarthritis patients ("osteoarthritis study") and a final study report that included, in a section pertaining to respite periods, the statement "[n]o investigator reported 'withdrawal syndrome' as an adverse experience during the respite periods." In a section entitled "Adverse Experiences by Body System During Respite Periods," the report's summary of the major results listed the most frequently reported adverse experiences in respite periods to be nervousness, insomnia, nausea, pain, anxiety, depression, and diarrhea, followed by the statement: "Twenty-eight patients (26%) had symptoms recorded during 1 or more respite periods."

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30. On or about February 12, 1999, certain supervisors and employees of a United Kingdom company affiliated with PURDUE provided certain PURDUE supervisors and employees with an analysis of the osteoarthritis study together with another clinical study. This analysis included a list of eight patients in the osteoarthritis study and eleven patients in the other study "who had symptoms recorded that may possibly have been related to opioid withdrawal," including one patient in the other study who required treatment for withdrawal syndrome. The "Discussion" section of this analysis included the following: "It is not surprising that some patients in the clinical trials developed some degree of physical dependence and consequently experienced withdrawal symptoms as a result of abrupt discontinuation of OxyContin tablets. All patients who were

suspected to have withdrawal symptoms have been reported but this may have resulted in a falsely high incidence. Of the patients who participated in [the osteoarthritis study] (in which patients entered respite periods without OxyContin tablets) many symptoms suspected to be due to opioid withdrawal may simply have resulted from the return of pain. After withdrawal of OxyContin tablets, patient 6007 complained of nervousness, patient 2004 complained of insomnia and felt restless and patients 2020 and 2028 were restless and anxious. Since these are symptoms which often accompany the return of significant pain, it may be wrong to label these as withdrawal symptoms. Nonetheless, the incidence of withdrawal syndromes in patients treated with OxyContin tablets is a concern and it is safer to over report, than under report this potential problem." The analysis' conclusions included the statement: "As expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided."

31. Certain PURDUE supervisors and employees participated in the drafting of an article regarding the osteoarthritis study that was published in a medical journal on or about March 27, 2000 ("osteoarthritis study article"). The "Results" section of the article included the following three statements pertaining to the incidence of withdrawal syndrome and withdrawal symptoms experienced by study patients: (1) One patient was hospitalized "for withdrawal symptoms . . . . The patient who was hospitalized with withdrawal symptoms had completed the study on the previous day and had been receiving CR oxycodone, 70 mg/d; symptoms resolved after 3 days." (2) "A second patient, who was receiving 60 mg/d CR oxycodone, experienced withdrawal symptoms after running out of study medication. The patient had not reported withdrawal symptoms during scheduled respites from doses of 30 or 40 mg/d." (3) "Withdrawal syndrome was not reported as

an adverse event for any patient during scheduled respites. Adverse experiences reported by more than 10% of patients during scheduled respites were nervousness (9 patients) and insomnia (8 patients)."

32. The osteoarthritis study article also included a "Comment" section. The statement regarding withdrawal in this section largely summarized the information in the three statements in the "Results" section and further suggested that patients taking low doses could have their OxyContin treatment abruptly discontinued without experiencing withdrawal if their condition so warranted: "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites, indicating that [OxyContin] at doses below 60 mg [per day] can be discontinued without tapering the dose if the patient's condition so warrants."

33. On or about May 18, 2000, after millions of OxyContin tablets had been sold and used by patients, PURDUE's Medical Services Department reported to certain PURDUE supervisors and employees that it had recently received a report of a patient who said he or she was unable to stop taking OxyContin 10 mg every 12 hours without experiencing withdrawal symptoms and the report indicated that "this type of question, patients not being able to stop OxyContin without withdrawal symptoms has come up quite a bit here in Medical Services lately (at least 3 calls in the last 2 days)."

34. On or about June 26, 2000, certain PURDUE supervisors and employees sent the full text of the osteoarthritis study article together with a "marketing tip" to PURDUE's entire sales force. The marketing tip stated that a reprint of the osteoarthritis study article was available for use in achieving sales success. The marketing tip also included as one of the article's twelve key points:

"There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR oxycodone at doses below 60 mg/d can be discontinued without tapering the dose if the patient condition so warrants."

35. On or about February 13, 2001, certain PURDUE supervisors and employees received a review of the accuracy of the withdrawal data in the osteoarthritis study that stated: "Upon a review of all comments for all enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms." This was followed by a list of eleven study patients who reported adverse experience due to possible withdrawal symptoms during these periods. 106 patients initially participated in the osteoarthritis study, 32 of them withdrew because of adverse events (not necessarily related to withdrawal), and 38 patients remained in the study at 12 months.

36. On or about March 28, 2001, a PURDUE employee emailed a PURDUE supervisor regarding the review of withdrawal data described in paragraph 35 of the Introduction of this Information, asking: "Do you think the withdrawal data from the [osteoarthritis] study . . . is worth writing up (an abstract)? Or would this add to the current negative press and should be deferred?" The supervisor responded: "I would not write it up at this point." No abstract was prepared.

37. Between approximately June 26, 2000, and June 30, 2001, certain PURDUE supervisors and employees distributed copies of the reprint of the osteoarthritis study article to all of PURDUE's sales representatives for use in the promotion and marketing of OxyContin to health care providers, including the distribution of 10,615 copies to certain PURDUE sales representatives between February 13, 2001, and June 30, 2001.

38. During the period June 26, 2000, through June 30, 2001, certain PURDUE sales representatives distributed the reprint of the osteoarthritis study article to some health care providers and falsely or misleadingly stated that patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms and that patients on such doses would not develop tolerance.

Misbranding of OxyContin: Use of Reduced Abuse Liability Claim in Marketing

39. The original OxyContin package insert approved by the FDA stated: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug" (the *Reduced Abuse Liability Statement*). Certain PURDUE supervisors and employees instructed PURDUE sales representatives to use this statement to market and promote OxyContin.

40. Certain PURDUE sales representatives, while promoting and marketing OxyContin, falsely told some health care providers that the *Reduced Abuse Liability Statement* meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

41. By March 2000, various PURDUE supervisors and employees in different parts of the company had received reports of OxyContin abuse and diversion occurring in different communities.

42. On or about November 27, 2000, certain PURDUE supervisors and employees amended the *Reduced Abuse Liability Statement* to state that "[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is believed to reduce the abuse liability of a drug," and instructed PURDUE sales representatives to use the amended statement to

promote and market OxyContin.

43. From March 2000 through June 30, 2001, certain PURDUE sales representatives, while promoting and marketing OxyContin, falsely told some health care providers that the *Reduced Abuse Liability Statement* and the amended statement meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

COUNT ONE
Introduction of Misbranded Drug into Interstate Commerce
21 U.S.C. §§ 331(a), 352(a), 333(a)(2)

1. The Introduction of this Information is realleged and made a part of this Count.

2. In or about and between January 1996 and June 30, 2001, in the Western District of Virginia and elsewhere, defendant The PURDUE FREDERICK COMPANY, INC. doing business as The Purdue Frederick Company, with the intent to defraud or mislead, introduced and caused the introduction into interstate commerce of quantities of OxyContin from various locations outside the state of Virginia to various locations in the Western District of Virginia and elsewhere, which were misbranded within the meaning of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(a), in that the matters described in paragraphs 19 through 43 of the Introduction of this Information constituted labeling within the meaning of 21 U.S.C. § 321(m) and were false and/or misleading.

All in violation of 21 U.S.C. §§ 331(a), 352(a), and 333(a)(2).

COUNT TWO
Introduction of Misbranded Drug in Interstate Commerce
21 U.S.C. §§ 331(a), 352(a), and 333(a)(1)

The United States Attorney charges that:

1. The Introduction of this Information is realleged and made a part of this Count.

2. Between in or about January 1996 and on or about June 30, 2001, defendants MICHAEL FRIEDMAN, HOWARD R. UDELL, and PAUL D. GOLDENHEIM, were senior executives of The PURDUE FREDERICK COMPANY, INC., doing business as The Purdue Frederick Company, and were responsible corporate officers under 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a) during the time that THE PURDUE FREDERICK COMPANY, INC., introduced and caused the introduction into interstate commerce of quantities of OxyContin from various locations outside the state of Virginia to various locations in the Western District of Virginia and elsewhere, which were misbranded as described in paragraphs 19 through 43 of the Introduction and Count One of this Information.

All in violation of Title 21, United States Code, Sections 331(a), 352(a), and 333(a)(1).

Date: May 9, 2007

John L. Brownlee
John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
ABINGDON DIVISION

UNITED STATES OF AMERICA	)	
	)	
v.	)	Dkt. No. _____
	)	
THE PURDUE FREDERICK COMPANY, INC.	)	
D/B/A The Purdue Frederick Company	)	
MICHAEL FRIEDMAN	)	
HOWARD R. UDELL	)	
PAUL D. GOLDENHEIM	)	

AGREED STATEMENT OF FACTS

Introduction

1. Defendant The PURDUE FREDERICK COMPANY, INC. (referred to in this Agreed Statement of Facts as "PURDUE"), doing business as The Purdue Frederick Company, was a New York corporation, headquartered in Connecticut. It was created in 1892 and was purchased by its current owners in 1952. At all times relevant to this Agreed Statement of Facts, PURDUE and other related and associated entities were engaged in the pharmaceutical business throughout the United States.

2. PURDUE developed and originally marketed OxyContin Tablets ("OxyContin"), an opioid analgesic approved to be taken every twelve hours. OxyContin is a controlled-release form of oxycodone and is a Schedule II controlled substance with an abuse liability similar to morphine.

3. Defendant MICHAEL FRIEDMAN joined PURDUE in 1985 as Vice President and Assistant to the President and Chairman. He was appointed Group Vice President in 1988, Executive Vice President and Chief Operating Officer in 1999, and President and Chief Executive Officer in 2003.

4. Defendant HOWARD R. UDELL joined PURDUE in 1977 as General Counsel. He was appointed Group Vice President and General Counsel in 1989, Executive Vice President and General Counsel in 1999, and Executive Vice President and Chief Legal Officer in 2003.

5. Defendant PAUL D. GOLDENHEIM joined PURDUE in 1985 as Medical Director. He was appointed Vice President and Medical Director in 1986, Vice President of Scientific and Medical Affairs and Executive Director of Purdue Frederick Research Center in 1988, Group Vice President of Scientific and Medical Affairs in 1989, Executive Vice President of Medical and Scientific Affairs in 1999, Executive Vice President of Worldwide Research & Development in 2000, and Executive Vice President of Worldwide Research & Development and Chief Scientific Officer in 2003. He left PURDUE in 2004.

6. From January 1996 through June 30, 2001, PURDUE received approximately $2.8 billion in revenue from the sale of OxyContin.

Statutory Framework

7. The United States Food and Drug Administration ("FDA") is the agency of the United States responsible for protecting the public health by ensuring the safety, efficacy, and security of human drugs and for enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301, *et seq.*

8. The FDCA, 21 U.S.C. § 355, required a sponsor of a new drug to receive FDA approval of a New Drug Application ("NDA"), before the sponsor could distribute the drug in interstate commerce.

9. The FDCA, 21 U.S.C. § 321(m), defined labeling to include "all labels and other written, printed, or graphic matter . . . accompanying [a drug]." Title 21, Code of Federal

Regulations, Section 202.1(*l*)(2) provided that labeling included brochures, booklets, mailing pieces, detailing pieces, bulletins, letters, motion picture films, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug which were disseminated by or on behalf of a drug's manufacturer, packer, or distributor. Such items "accompanied" a drug if they were designed for use and used in the distribution and sale of the drug.

10. The FDCA, 21 U.S.C. § 352(a), provided that a drug was misbranded "[i]f its labeling [was] false or misleading in any particular." The FDCA, 21 U.S.C. § 321(n), provided that "[i]n determining whether the labeling . . . [was] misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representation or material with respect to the consequences which may result from the use . . . to which the labeling . . . relates under the conditions of use prescribed in the labeling . . . or under such conditions of use as are customary or usual."

11. The FDCA, 21 U.S.C. § 331(a), prohibited the introduction or delivery for introduction into interstate commerce of a misbranded drug. 21 U.S.C. § 333(a)(2) provided that such a violation committed with the intent to defraud or mislead was punishable as a felony. Under 21 U.S.C. § 333(a)(1) and the applicable case law, an individual could be held criminally liable for a misdemeanor violation of § 331(a) without having knowledge of, or intent to cause, the misbranding if that individual was a responsible corporate officer at the time of the misbranding. A responsible corporate officer for these purposes was one who had responsibility and authority either to prevent in the first instance or to promptly correct certain conduct resulting in the misbranding of a drug introduced or delivered for introduction into interstate commerce.

12. OxyContin was a drug within the meaning of the FDCA, 21 U.S.C. § 321(g)(1), and a new drug within the meaning of 21 U.S.C. § 321(p).

OxyContin Approval and Package Insert

13. On approximately December 28, 1994, PURDUE submitted the OxyContin NDA to the FDA. The NDA included clinical studies showing that OxyContin, when dosed every twelve hours, was as safe and as effective as immediate-release oxycodone dosed every six hours.

14. The NDA did not claim that OxyContin was safer or more effective than immediate-release oxycodone or other pain medications and PURDUE did not have, and did not provide the FDA with, any clinical studies demonstrating that OxyContin was less addictive, less subject to abuse and diversion, or less likely to cause tolerance and withdrawal than other pain medications.

15. On or about October 24, 1995, the FDA completed, with PURDUE's assistance, an internal Medical Officer Review ("MOR") of the Integrated Summary of Safety ("ISS") and a MOR of the Integrated Summary of Efficacy ("ISE"). While not binding on the company, the MORs were disclosed to certain PURDUE supervisors and employees. These MORs did not state that OxyContin was more effective than or superior to, safer, had less opioid effects, or caused fewer adverse events than any other marketed product.

16. The MOR of the ISS included these statements:

a. "The blood level data in clinical use suggests the opioid effects [of OxyContin and immediate-release oxycodone] would be similar;"

b. "The best conclusion is that the efficacy of [OxyContin] is equivalent to the [immediate-release oxycodone], with an adverse event profile that is as good as the [immediate-release oxycodone]. I would not allow a 'better' claim." (emphasis in original);

c. "The adverse experience profile of [OxyContin] is qualitatively similar to that of the parent drug, oxycodone;" and

d. "Withdrawal is possible in patients who have their dosage abruptly reduced or discontinued."

17. The MOR of the ISE included these statements:

a. "There is some evidence, both pharmacokinetic and clinical, that reduced acute opioid adverse effects may be expected in some patients, but there is not enough evidence to support an [adverse event] superiority claim [for OxyContin] against other marketed products." (emphasis in original); and

b. "Care should be taken to limit competitive promotion. [OxyContin] has been shown to be as good as current therapy, but has not been shown to have a significant advantage beyond reduction in frequency of dosing."

18. The FDA approved the OxyContin NDA on December 12, 1995, and from 1996 through June 30, 2001, the FDA-approved package insert for OxyContin stated that it was intended for "the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days." The package insert also included the statement: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."

Misbranding of OxyContin

19. During the period February through March 1995, PURDUE supervisors and employees obtained market research that included focus groups of forty primary care physicians, rheumatologists, and surgeons to determine their receptivity to using OxyContin for non-cancer pain. According to this market research, some of these physicians had concerns, similar to their concerns about combination opioids, regarding OxyContin's addictive potential and side effect profile, including that "[t]he biggest negative of [OxyContin] was the abuse potential."

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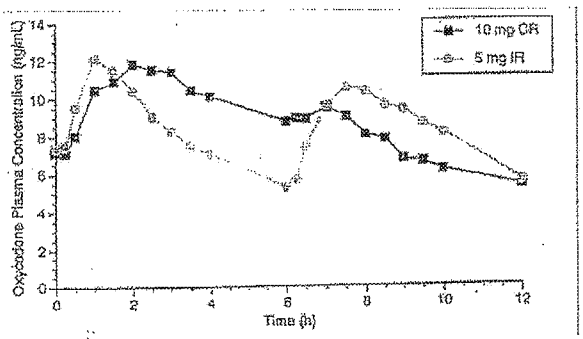

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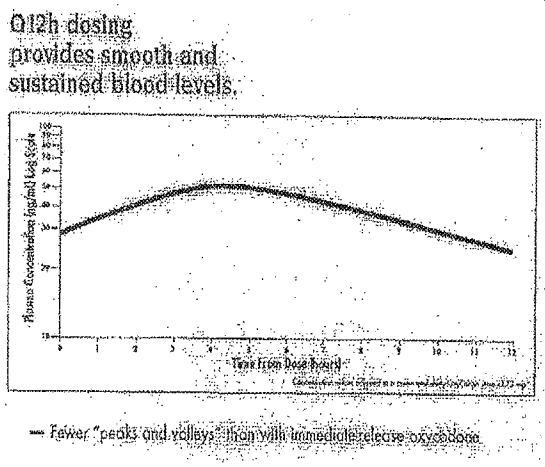

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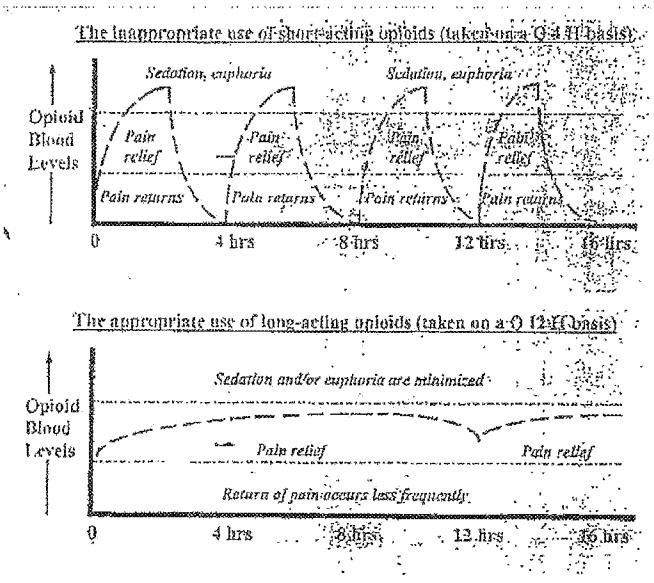

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publications, conventions, or communications with the field force that would affect the unique position that OxyContin ha[d] in many physicians mind (*sic*)."

30. On or about February 12, 1999, certain supervisors and employees of a United Kingdom company affiliated with PURDUE provided certain PURDUE supervisors and employees with an analysis of the osteoarthritis study together with another clinical study. This analysis included a list of eight patients in the osteoarthritis study and eleven patients in the other study "who had symptoms recorded that may possibly have been related to opioid withdrawal," including one patient in the other study who required treatment for withdrawal syndrome. The "Discussion" section of this analysis included the following: "It is not surprising that some patients in the clinical trials developed some degree of physical dependence and consequently experienced withdrawal symptoms as a result of abrupt discontinuation of OxyContin tablets. All patients who were suspected to have withdrawal symptoms have been reported but this may have resulted in a falsely high incidence. Of the patients who participated in [the osteoarthritis study] (in which patients entered respite periods without OxyContin tablets) many symptoms suspected to be due to opioid withdrawal may simply have resulted from the return of pain. After withdrawal of OxyContin tablets, patient 6007 complained of nervousness, patient 2004 complained of insomnia and felt restless and patients 2020 and 2028 were restless and anxious. Since these are symptoms which often accompany the return of significant pain, it may be wrong to label these as withdrawal symptoms. Nonetheless, the incidence of withdrawal syndromes in patients treated with OxyContin tablets is a concern and it is safer to over report, than under report this potential problem." The analysis' conclusions included the statement: "As expected, some patients did become physically dependent on OxyContin tablets but this is not expected to be a clinical problem so long as abrupt withdrawal of drug is avoided."

31. Certain PURDUE supervisors and employees participated in the drafting of an article regarding the osteoarthritis study that was published in a medical journal on or about March 27, 2000 ("osteoarthritis study article"). The "Results" section of the article included the following three statements pertaining to the incidence of withdrawal syndrome and withdrawal symptoms experienced by study patients: (1) One patient was hospitalized "for withdrawal symptoms . . . . The patient who was hospitalized with withdrawal symptoms had completed the study on the previous day and had been receiving CR oxycodone, 70 mg/d; symptoms resolved after 3 days." (2) "A second patient, who was receiving 60 mg/d CR oxycodone, experienced withdrawal symptoms after running out of study medication. The patient had not reported withdrawal symptoms during scheduled respites from doses of 30 or 40 mg/d." (3) "Withdrawal syndrome was not reported as an adverse event for any patient during scheduled respites. Adverse experiences reported by more than 10% of patients during scheduled respites were nervousness (9 patients) and insomnia (8 patients)."

32. The osteoarthritis study article also included a "Comment" section. The statement regarding withdrawal in this section largely summarized the information in the three statements in the "Results" section and further suggested that patients taking low doses could have their OxyContin treatment abruptly discontinued without experiencing withdrawal if their condition so warranted: "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites, indicating that [OxyContin] at doses below 60 mg [per day] can be discontinued without tapering the dose if the patient's condition so warrants."

33. On or about May 18, 2000, after millions of OxyContin tablets had been sold and used by patients, PURDUE's Medical Services Department reported to certain PURDUE supervisors and

employees that it had recently received a report of a patient who said he or she was unable to stop taking OxyContin 10 mg every 12 hours without experiencing withdrawal symptoms and the report indicated that "this type of question, patients not being able to stop OxyContin without withdrawal symptoms has come up quite a bit here in Medical Services lately (at least 3 calls in the last 2 days)."

34. On or about June 26, 2000, certain PURDUE supervisors and employees sent the full text of the osteoarthritis study article together with a "marketing tip" to PURDUE's entire sales force. The marketing tip stated that a reprint of the osteoarthritis study article was available for use in achieving sales success. The marketing tip also included as one of the article's twelve key points: "There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites indicating that CR oxycodone at doses below 60 mg/d can be discontinued without tapering the dose if the patient condition so warrants."

35. On or about February 13, 2001, certain PURDUE supervisors and employees received a review of the accuracy of the withdrawal data in the osteoarthritis study that stated: "Upon a review of all comments for all enrolled patients, it was noted that multiple had comments which directly stated or implied that an adverse experience was due to possible withdrawal symptoms." This was followed by a list of eleven study patients who reported adverse experience due to possible withdrawal symptoms during these periods. 106 patients initially participated in the osteoarthritis study, 32 of them withdrew because of adverse events (not necessarily related to withdrawal), and 38 patients remained in the study at 12 months.

36. On or about March 28, 2001, a PURDUE employee emailed a PURDUE supervisor regarding the review of withdrawal data described in paragraph 35 of this Agreed Statement of Facts,

asking: "Do you think the withdrawal data from the [osteoarthritis] study . . . is worth writing up (an abstract)? Or would this add to the current negative press and should be deferred?" The supervisor responded: "I would not write it up at this point." No abstract was prepared.

37. Between approximately June 26, 2000, and June 30, 2001, certain PURDUE supervisors and employees distributed copies of the reprint of the osteoarthritis study article to all of PURDUE's sales representatives for use in the promotion and marketing of OxyContin to health care providers, including the distribution of 10,615 copies to certain PURDUE sales representatives between February 13, 2001, and June 30, 2001.

38. During the period June 26, 2000, through June 30, 2001, certain PURDUE sales representatives distributed the reprint of the osteoarthritis study article to some health care providers and falsely or misleadingly stated that patients taking OxyContin at doses below 60 milligrams per day can always be discontinued abruptly without withdrawal symptoms and that patients on such doses would not develop tolerance.

Misbranding of OxyContin: Use of Reduced Abuse Liability Claim in Marketing

39. The original OxyContin package insert approved by the FDA stated: "Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug" (the *Reduced Abuse Liability Statement*). Certain PURDUE supervisors and employees instructed PURDUE sales representatives to use this statement to market and promote OxyContin.

40. Certain PURDUE sales representatives, while promoting and marketing OxyContin, falsely told some health care providers that the *Reduced Abuse Liability Statement* meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used

to "weed out" addicts and drug seekers.

41. By March 2000, various PURDUE supervisors and employees in different parts of the company had received reports of OxyContin abuse and diversion occurring in different communities.

42. On or about November 27, 2000, certain PURDUE supervisors and employees amended the *Reduced Abuse Liability Statement* to state that "[d]elayed absorption, as provided by OxyContin tablets, when used properly for the management of pain, is believed to reduce the abuse liability of a drug," and instructed PURDUE sales representatives to use the amended statement to promote and market OxyContin.

43. From March 2000 through June 30, 2001, certain PURDUE sales representatives, while promoting and marketing OxyContin, falsely told some health care providers that the *Reduced Abuse Liability Statement* and the amended statement meant that OxyContin did not cause a "buzz" or euphoria, caused less euphoria, had less addiction potential, had less abuse potential, was less likely to be diverted than immediate-release opioids, and could be used to "weed out" addicts and drug seekers.

Introduction of Misbranded OxyContin Into Interstate Commerce

44. In or about and between January 1996 and June 30, 2001, PURDUE manufactured, marketed, and sold quantities of OxyContin in interstate commerce from various locations outside the state of Virginia to various locations in the Western District of Virginia and elsewhere, which were misbranded within the meaning of 21 U.S.C. §§ 331(a), 333(a)(2), and 352(a), as described in paragraphs 19 through 43 of this Agreed Statement of Facts.

45. Between in or about January 1996 and on or about June 30, 2001, defendants MICHAEL FRIEDMAN, HOWARD R. UDELL, and PAUL D. GOLDENHEIM, were responsible

corporate officers of PURDUE under 21 U.S.C. §§ 331(a), 333(a)(1), and 352(a).

46. Defendants MICHAEL FRIEDMAN, HOWARD R. UDELL, and PAUL D. GOLDENHEIM ("individual defendants") do not agree that they had personal knowledge of all of the matters set forth in paragraphs 1 through 44 of this Agreed Statement of Facts. However, they agree that the Court may accept these facts, as agreed to by defendant THE PURDUE FREDERICK COMPANY, INC., as part of the factual basis supporting the guilty pleas by the individual defendants.

The parties agree to the foregoing Agreed Statement of Facts.

Date: May 9, 2007

FOR THE UNITED STATES:

John L. Brownlee

John L. Brownlee
United States Attorney
Western District of Virginia

Rick A. Mountcastle, Assistant United States Attorney
Randy Ramseyer, Assistant United States Attorney
Sharon Burnham, Assistant United States Attorney
Barbara T. Wells, Trial Attorney, U.S. Dept. Of Justice
Elizabeth Stein, Trial Attorney, U.S. Dept. Of Justice

FOR DEFENDANT THE PURDUE FREDERICK COMPANY, INC.:

Date: May 7, 2007

Robin E. Abrams, Esquire
Vice-President and Director of
The Purdue Frederick Company, Inc. and
Vice-President and Associate General Counsel
of Purdue Pharma L.P.
Authorized Corporate Officer for
The Purdue Frederick Company, Inc.

Date: May 8, 2007

Howard M. Shapiro, Esquire
Counsel for The Purdue Frederick Company, Inc.

FOR DEFENDANT MICHAEL FRIEDMAN:

Date: May 7, 2007

Michael Friedman, Defendant

Date: _____

Mark D. Pomerantz, Esquire
Counsel for Michael Friedman

FOR DEFENDANT HOWARD R. UDELL:

Date: May 7, 2007

Howard R. Udell, Defendant

Date: _____

Mary Jo White, Esquire
Counsel for Howard R. Udell

FOR DEFENDANT PAUL D. GOLDENHEIM:

Date: _____

Paul D. Goldenheim, Defendant

Date: _____

Andrew Good, Esquire
Counsel for Paul D. Goldenheim

FOR DEFENDANT THE PURDUE FREDERICK COMPANY, INC.:

Date: _____

Robin E. Abrams, Esquire
Vice-President and Director of
The Purdue Frederick Company, Inc. and
Vice-President and Associate General Counsel
of Purdue Pharma L.P.
Authorized Corporate Officer for
The Purdue Frederick Company, Inc.

Date: _____

Howard M. Shapiro, Esquire
Counsel for The Purdue Frederick Company, Inc.

FOR DEFENDANT MICHAEL FRIEDMAN:

Date: 5/7/07

Michael Friedman, Defendant

Date: 5/8/07

Mark B. Pomerantz, Esquire
Counsel for Michael Friedman

FOR DEFENDANT HOWARD R. UDELL:

Date: _____

Howard R. Udell, Defendant

Date: _____

Mary Jo White, Esquire
Counsel for Howard R. Udell

FOR DEFENDANT PAUL D. GOLDENHEIM:

Date: _____

Paul D. Goldenheim, Defendant

Date: _____

Andrew Good, Esquire
Counsel for Paul D. Goldenheim

FOR DEFENDANT THE PURDUE FREDERICK COMPANY, INC.:

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Authorized Corporate Officer for
The Purdue Frederick Company, Inc.

Date: _____

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Counsel for The Purdue Frederick Company, Inc.

FOR DEFENDANT MICHAEL FRIEDMAN:

Date: _____

Michael Friedman, Defendant

Date: _____

Mark D. Pomerantz, Esquire
Counsel for Michael Friedman

FOR DEFENDANT HOWARD R. UDELL:

Date: 5/7/07

Howard R. Udell, Defendant

Date: 5/8/07

Mary Jo White, Esquire
Counsel for Howard R. Udell

FOR DEFENDANT PAUL D. GOLDENHEIM:

Date: _____

Paul D. Goldenheim, Defendant

Date: _____

Andrew Good, Esquire
Counsel for Paul D. Goldenheim

FOR DEFENDANT THE PURDUE FREDERICK COMPANY, INC.:

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Robin E. Abrams, Esquire
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Authorized Corporate Officer for
The Purdue Frederick Company, Inc.

Date: _____

Howard M. Shapiro, Esquire
Counsel for The Purdue Frederick Company, Inc.

FOR DEFENDANT MICHAEL FRIEDMAN:

Date: _____

Michael Friedman, Defendant

Date: _____

Mark D. Pomerantz, Esquire
Counsel for Michael Friedman

FOR DEFENDANT HOWARD R. UDELL:

Date: _____

Howard R. Udell, Defendant

Date: _____

Mary Jo White, Esquire
Counsel for Howard R. Udell

FOR DEFENDANT PAUL D. GOLDENHEIM:

Date: May 8, 2007

Paul D. Goldenheim, Defendant

Date: May 8, 2007

Andrew Good, Esquire
Counsel for Paul D. Goldenheim